S. T.O.P.

Safe Tables Our Priority

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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Docket No. 97 N-0074

Safe Tables Our Priority is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. S. T. O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We count among our members victims of *E.* co/i 0157:H7 contaminated meat, lettuce and apple juice; hepatitis A contaminated strawberries; *Vibrio vulnificus* in oysters; *Salmonella* contaminated poultry and eggs; and *Campylobacter* contaminated poultry. In all of these cases, the dangers of potentially contami nated products were known to government. And in all of these cases, inadequate efforts by government to warn consumers failed to protect them from life threatening i l lnesses.

We are submitting these comments today as an addendum to previous public comments we have submitted on the topic of the Food Safety Strategy and to conversations we have had with FDA. S. T.O. P. is particularly interested in FDA standardizing its approach to food safety with an eye toward making the organization more efficient and effective.

Our comments today are organized as follows:

1. The Need for A Standardized Definition of At-Risk Groups

Under FDA's current system, every time a safety issue arises in a different food, FDA reevaluates who qualifies as "at-r isk." To increase overal l agency efficiency, saving both

time and money, S. T.O.P. strongly advises that FDA develop, in conjunction with USDA and the CDC, a standardized position on which people are considered at-risk from different foodborne illnesses and hence from different foods. Under the current system, every time a specific food fails under FDA scrutiny, FDA examines the at-risk group question over again (for example, first for juice, next for alfalfa sprouts). In reality, certain groups of consumers are at-risk for particular pathogens regardless of the type of food in which the microbes are found. Standardized, expanded definitions of the at-risk groups would enable FDA to more efficiently implement labeling rules and to more effectively help consumers identify whether or not they fall into these categories through FDA's public relations and targeted marketing efforts. We believe that these types of decisions are too important to be relegated to the back seat of every food safety issue.

A. Expanded Descriptions of Existing Acknowledged At-Risk Groups

Who should be concerned about oysters? Who should be concerned about unpasteurized juices? While it might be sufficient to say "immune impaired" on a label, consumers need a medically and scientifically determined definition as to whether they fall into each category. S. T.O. P. has pointed out that people on antibiotics and antacids are more at-risk than the general population, though they would not necessarily characterize themselves as "immune impaired." Antibiotics can wipe out healthy bacteria in the gut that compete with harmful bacteria and otherwise keep them from growing out of control. Antacids reduce the acidity of the stomach, allowing less acid resistant organisms to pass through to the gut. S. T.O. P. recently voiced objections to the term "elderly" over the term "seniors" in labeling language due to the concern that consumers would not understand whether or not they qualified as elderly. We would like to see FDA/CDC publish an expanded definition for added clarity. These matters are of life threatening urgency.

B. Acknowledgment of Link Between Listeria and Other Fecal-Based Pathogens

Of particular concern has been FDA's reluctance to include "pregnant women" as an "at-risk group" for unpasteurized juices.,. or for other foods known to harbor fecal contamination.

In the juice labeling final rule, FDA referred to the CAST report which described the complications of *Listeria monocytogenes* as "miscarriage." This term is inaccurate and underrates the severity of the consequences of a *Listeria* infection. According to Webster's Third New International Dictionary the definition is: **"a:** expulsion of a human fetus before it is viable esp. between the 12th and 28th weeks of gestation --compare ABORTION, PREMATURE DELIVERY b: abortion esp. when due to natural causes." Babies that are quite viable can be terminated in utero by a *Listeria* infection up to the point when they are considered full term. Babies that are born either premature y or at term with a *Listeria* infection can develop meningitis. *Listeria* is known to have a high mortality rate.

Particularly insidious about a *Listeria* infection is the fact that: "Symptomatic fecal carriage is common in humans (up to 10%)...".[i] According to the USDA, not all doctors know the symptoms even when they do appear.[ii] Recent USDA-related recalls[iii] have demonstrated that when government enforces its zero tolerance for *Listeria,* vast quantities of food are found to be contaminated with the organism. These factors, combined with all the standard issues surrounding underreporting of foodborne illness, suggest that there is high probability that all *Listeria*-related illness and fetal demise are grossly underreported.

When an FDA-overseen food has been linked to multiple types (e.g. ***E. coli0157:H7*** and *Salmonella*) of feces-sourced contamination, it has also been connected *to Listeria monocytogenes.* The two produce-related foods which have caused FDA to take the greatest action in recent years are alfalfa sprouts and unpasteurized juices. Both have experienced repeated outbreaks of *Salmonella* and ***E. coli*** 01 57:H7. FDA investigations in 1997-1998 of unpasteurized apple juice found a 14°/0 generic ***E. coli*** or fecal coliform contamination rate in samples tested.[iv] Tests by USDA and the Florida Department of Agriculture conducted between 1996 and 1998 have yielded a generic fecal contamination rate of 40/0 of samples or 50/0 of firms in unpasteurized citrus juice."

In both unpasteurized juices and alfalfa sprouts, *Listeria* has been found as well. Alfalfa sprouts were recalled in September of 1998 for *Listeria* contamination." It has been reported that *Listeria* was found in Odwalla-brand juice by Odwalla quality assurance employees prior to that company's unpasteurized apple juice outbreak/recall.[vii] The San Jose Mercury News article which describes the finding of *Listeria* in Odwalla's unpasteurized juices, indicates that tests found *Listeria* "in about five samples of apple juice and two in orange juice." They also found evidence that *Listeria* was on the fruit. Based on FDA's investigation of the Odwalla outbreak, it is possible that FDA may have further data on this particular incident. The same article indicates:

> "Dr. Douglas L. Archer, an Odwalla consultant and former deputy director of the FDA's Center for Food Safety and Applied Nutrition, said that some listeria is likely to be found in any juice if enough of it is tested."

We presume because the article focused on unpasteurized juices that his comment is directed at insufficiently pasteurized juices. This combination of opinion and data suggests that *Listeria* will be found in unpasteurized juices if only FDA would test for it.

FDA's argument against including pregnant women in that at-risk groups for unpasteurized juice warnings labels noted:

> "FDA acknowledges that the CAST report noted that the immune system of a pregnant woman is altered to some extent compared to that of a non-pregnant woman. In looking at the populations at greatest risk from foodborne pathogens, CAST identified pregnant women as a group at risk from L. monocytogenes, a widely distributed pathogen that has been associated with miscarriages. Nonetheless, there is not evidence that pregnant women or their fetuses are at any greater risk of serious illness from the foodborne pathogens associated with juices than the general population. The agency notes that Listeria has not been identified in the documented cases of illness associated with consumption of untreated juices."

In trying to understand FDA's response, S. T.O. P. asked Dr. Larry Pickering of the Center for Pediatric Research in Norfolk, VA whether pregnant women are considered more susceptible to diarrheal illnesses, his area of specialty. Dr. Pickering, who is a member of the infectious disease committee at the American Academy of Pediatrics, responded with the following:

> "Pregnant women are considered to be somewhat immune compromised during pregnancy. With regard to foodborne associated illness, maternal infection with several organisms has been associated with abortion, preterm delivery and other obstretic complications. Organisms of concern include Listeria, Campy lobacter, Salmonella, enterohemorrhagic E. coli, Yersinia and Brucella to name a few."[viii]

Pregnant women can and should be considered more susceptible to some foodborne illnesses than the general population.

With regards to *Listeria* in particular, we believe that FDA must seriously consider the probability of *Listeria* contamination in unpasteurized juice. According to the Control of Communicable Diseases Manual, asymptomatic fecal carriage of *Listeria* is also common in animals.[ix] Hence, ***E. coli0157:H7,*** *Salmonella* and *Listeria* all can share a common originating point of contamination: animal feces, *Listeria* is also considered more heat resistant than ***E. coli*** 01 57:H7 and is better able to withstand environmental stresses.' Therefore, where multiple fecal pathogens have been found in foods due to insufficient sanitation or killsteps, *Listeria* can survive as well and follow the same route into the final food product.

At present, there are NO materials published by the CDC or FDA that alert pregnant women to the risks of contamination in unpasteurized juices. S. T.O. P. does not believe that FDA's public health risk assessment requires that people's illnesses and deaths must be genetically fingerprinted to a specific food before FDA can take action. S. T.O. P. implores the FDA to consider pregnant women as a separate at-risk group for foods that show repeated fecal contamination and urgently requests that FDA add "pregnant women" to the at-risk groups listed in warning labels for unpasteurized juices.

II. The Need for Standardized Labeling as A Form of Notification

In its combination of juice labeling and juice HACCP requirements, FDA has unevenly and inadequately warned consumers of unpasteurized juices by only addressing packaged products. Restaurants, juice bars, and small businesses have been exempted from the Proposed Rule.

S. T.O.P. points out that as other repeatedly contaminated foods, particularly produce-related foods, are identified, this issue of which final products should bear warning labels will arise again and again. Because the pathogenic safety of a product received by consumers is rarely related to the package in which the consumer finally receives it, FDA needs to identify ways in which warnings can be applied to:

1) Bulk product sold in grocery stores
2) Products served in restaurants on plates or at salad bars
3) Products served in delis or juice bars.
4) Products sampled at farmers' markets.

If FDA does not have the jurisdiction to handles these areas, S. T.O. P. is interested in understanding who does and how that jurisdiction can be consolidated, through the Food Code, for example, to ensure that consumers received appropriate warnings at the point of sale.

III. The Need for HACCP Back to the Seed and Soil

S. T.O.P. strongly supports the extension of HACCP back to the seed and soil. A significant portion of initial produce contamination appears to happen in harvest (as when drop apples are used for unpasteurized juice), in irrigation (as when produce is sprayed with Cryptosporidium contaminated water), in ferti lization (as when alfalfa seed fields are fertilized with fluids from manure lagoons), and in growing (as when runoff from the nearby dairy farm invades crop lands). When using a safety performance criteria, it is virtually impossible to determine the safety quality of an output, such as minimally processed juices or alfalfa sprouts, if you have no control over the pathogen load on the input. FDA must take steps to ensure that in the next century, all crop growing farmers take steps to eliminate pathogen loads on their products by examining their critical control points.

IV. The Need for a Standardized Approach to Hazardous Foods

FDA's current approach to handling foods that have caused repeated outbreaks reinvents the wheel each time a repeatedly hazardous food is identified. Instead of treating each food as if it were its own, unusual situation, FDA should develop a standard procedure for how it will handle such foods, and it should make that procedure known to stakeholders. The objectives of creating such a procedure would be:

1) To ensure that FDA has a standardized mechanism to quickly and efficiently inform at-risk consumers of food hazards as they arise.

2) To encourage industry to look after its own bad producers by conveying how the entire industry will be treated if there are repeated outbreaks.

3) To speed up rulemaking on relatively unscientific regulations such as labels.

This would enable FDA to address many of the most basic issues that are applicable to all foods once in a roughly generic manner ("labeling language will generally look like this," "produce sold in bulk will be handled this way") and therefore make rulemaking more efficient.

An example process FDA might propose is, when a food is determined by FDA to be the repeated source of illness and therefore a public health threat, FDA would respond with the following:

1. Immediately:
   Issue a press release warning at-risk groups that the food is hazardous.
2. Immediately to one year afterward:
   Investigate hundreds of sites to identify safety issues in the industry
3. Within one month of press release:
   Hold a public meeting in Washington, DC with the NACMCF, industry and consumer groups
4. Within six months (including comment periods/OMB/etc.):
   Expedite a rule requiring warning labels
5. Within one year: Expedite a traceback labeling rule
6. Within 3 months: Initiate appropriate research
7. Within 6 months: Propose a HACCP rule

In S. T. O.P.'s opinion, current food safety conditions at the farm-level are insufficient to prevent repeated outbreaks. Over time, we are likely to learn that certain food growing/handling techniques make some foods more risky than the average. It is important to both consumers and industry that FDA have methods in place to handle these situations.

V. The Need for Standardized Messages, Appropriate to the Hazard

FDA's current public relations, marketing materials, and messages demonstrate a lack of cohesiveness and of priority setting. As a result, for the same amount of time and energy, they could be even more effective than they presently are.

One of the basic tenets of public relations and communications strategy is to establish what the most important messages are and repeat them. Establishing which messages are important helps to ensure that unimportant messages do not take up valuable mindshare on the part of the target audience or confuse the target audience with extraneous data. Repeating the important messages helps to ensure that they are received.

We would give the following examples of FDA's messaging over the last three years. in 1997, FDA produced a short piece entitled "Apple Cider Season Brings Caution," as part of its "FDA Reports, Facts from the U.S. Food & Drug Administration." This document says,

> "The Food and Drug Administration (FDA) advises people in the following high risk groups to drink only pasteurized cider and juices:
> - Children
> - Older adults
> - People with weakened immune systems, such as those with HIV, AIDS or cancer."

It also advises, "Children on field trips to apple cider mills or farm markets should not drink unpasteurized cider."

This very fundamental message, that the at-risk groups should drink ONLY pasteurized cider, does not appear **to have been clearly repeated** by FDA spokespeople to the press. In one article, Arthur Whitmore is described as having said:

> "'We want to make sure they understand that little kids really shouldn't be fed fresh juice, fresh apple juice in particular,' Whitmore said."[xi]

No mention is made of other at-risk groups. Yet in another, Whitmore gives only counsel about the wisdom of drinking unpasteurized juice, remarking about children's affection for unpasteurized apple juice:

> "'A lot of people are unaware [of the danger],' said Arthur Whitmore, spokesman for the U.S. Food and Drug Administration's nutritional department. 'They think it's a natural product. Kids love it. But if you really want to reduce your risk, it may not be wise to drink unpasteurized apple juice.'"[xii]

In 1998, the message "these at-risk groups should NOT drink unpasteurized juices, " was simply not found on FDA's glossy "What Consumers Need to KNOW About Juice Safety" sheet. Instead, a simi lar, expanded message addressing al l types of unpasteurized juice was placed on the ***second*** page as the answer to the *tenth* question in the "Questions and Answer on the Juice Warning Label Regulation," dated September 8, 1998, distributed in the same press kit.

In another example, an article in a spring 1998 newsletter to the White House daycare center,[xiii] growing alfalfa sprouts was suggested to parents as a great activity to do with children. Indeed, the article recommends "The trick is to buy alfalfa seeds that have not been chemically treated." At the time that this article ran, FDA already had data that indicated the alfalfa sprout seed is the likely source of pathogenic contamination which had already ki l led at least one person. Nevertheless, the message to parents was: sprouts are safe. Yet, in August, 1998, just four months later, FDA issued a statement indicating that alfalfa sprouts should not be consumed by children, the elderly and the immune impaired. Indeed, it would appear that the only currently available mechanism for improving the safety of alfalfa sprouts is chemically treating the seed.[xiv]

In July of 1998, FDA mentioned the following in its Final Juice Labeling Rule:

> "This assignment did not result in the detection of any pathogens in a finished cider product intended to be sold to the public. However, FDA's preliminary findings from this assignment show that one firm's incoming apples tested positive for Salmonella sp. indicating that microbial hazards that necessitate effective control measures are reasonably likely to occur on incoming apples. Moreover, FDA's preliminary findings show that fecal coliforms and E. coli were found in the wash water used at several firms, indicating that the water is of poor quality. In addition a small number of finished cider products tested positive for fecal coliforms and generic E. coli was found in 14 percent of the finished product samples."

Yet, rather than alert the public to these startling facts (that more than 1 in 10 samples were contaminated) which ***support*** FDA's position on unpasteurized juices, FDA did not publish this information outside of the Juice Labeling Final Rule. When news reports discussed that FDA had concluded its investigations, the only message repeated was that in all of FDA's investigations, ***E. co/i0157:H7*** was not found.

One potential mechanism that FDA could use to help ensure consistency of its communications efforts would be a sheet of messages for a specific food safety topic intended for internal use. These messages would be listed in order of priority based on the need for them to be repeated to and retained by the target audiences. As more data came in, such as the results of field studies, the message sheet could be revised so that data that reinforces the warnings would have higher priority. Whenever new materials or education campaigns were developed, they would be driven off of the most recent message sheets. Likewise, when existing nutritional statements were made, as in FDA's "Five A Day" campaign, the agency could ensure that the topmost safety messages were included.

VI. In Conclusion

Given FDA's need for increased resources to improve food safety, it is imperative that FDA use its existing resources as wisely as possible. Typically, when any organization runs into a series of events, they are initially treated as individual, unrelated events. From S. T. O.P.'s perspective, these events are related and until appropriate safeguards are introduced across all foods, they will continue to occur. We encourage FDA to take a more standardized approach to its definitions, its procedures, and its messages in order to improve the agency's overall efficiency and effectiveness.

Elaine Dodge
Executive Director

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Advisory Board Member

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[i] Benenson, Abram, *Control of* Communicable *Diseases* Manual, Sixteenth Edition, 1995; pages271 -272.

[ii] Lawson, Kate, "Tainted meat can infect your refrigerator," Detroit News, February 2, 1999: "'Last week we handled over 1,400 calls related to the recall,' says Diane Van, the team leader for the USDA's meat and poultry hotline, who says its busiest time is at Thanksgiving, 'but I'd have to say the recall questions have far surpassed that. We're even getting cal Is from doctors asking how to identify the symptoms.'"

[iii] Bill MarfSara Lee; Thorn Apple Valley; Land O The Lakes.

[iv] Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Final Rule; Federal Register: July 8, 1998 (Volume 63, Number 130), Pages 37029-37056.

[v] Transcript of Proceedings, FDA Technical Workshop,; Citrus Research and Education Center, University of Florida, Lake Alfred, Florida, November, 12, 1998; page 34.

[vi] Associated Press-Washington, "Sprout Recall, " September 5, 1998

[vii] Carey, Pete, "Testing Dispute Preceded TaintedOdwalla Juice", San Jose Mercury News, october31, 1997.

[viii] E-mail exchange with Dr. LarryPickering, Center for Pediatric Research, Norfolk, VA. February 8, 1999.

[ix] Benson, Abram, Ibid.

[x] Conversation with Dane Bernard, Senior Director, Food Safety Programs, National Food Processors Association.

[xi] Fox, Maggie, "U.S. FDA to Require Labels on Juice Risk ," Reuters, August 26, 1997.

[xii] Salemi, Tom, Hard pressed , "Small cider mills fear push for mandatory pasteurization," Boston Business Journal, October 28, 1997.

[xiii] Parent Pages, April 1998, Volume 9, Number 4, 1998 Pages, Inc. P.O. Box 6036, Colorado Springs, CO 80934, 719-632-0916.

[xiv] Public Meeting on Sprout Safety, September 28-29, Washington, DC.

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